PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PC32199A	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/IB2005/000610	International filing date *(day/month/year)* 04.03.2005	Priority date *(day/month/year)* 17.03.2004
International Patent Classification (IPC) or national classification and IPC A61K39/12, A61K39/295		
Applicant PHARMACIA & UPJOHN COMPANY LLC et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
18.04.2005	29.08.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Ulbrecht, M Telephone No. +49 89 2399-7710

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IB2005/000610

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-22	as originally filed

Claims, Numbers

1-8	as originally filed
9-18	received on 03.08.2005 with letter of 03.08.2005

Drawings, Sheets

1/1	as originally filed

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IB2005/000610

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-9 (with respect to IA)

because:

☒ the said international application, or the said claims Nos. 1-9 (with respect to IA) relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-18
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-18
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	10-18
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Supplemental Box relating to Sequence Listing

Continuation of Box I, item 2:

1. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this report has been established on the basis of:

   a. type of material:

   ☒ a sequence listing

   ☒ table(s) related to the sequence listing

   b. format of material:

   ☒ in written format

   ☒ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed

   ☐ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purposes of search and/or examination

   ☐ received by this Authority as an amendment on

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional observations, if necessary:

Re item III.

Claims 1-9 relate to subject-matter considered by this Authority to be covered by the provisions of R. 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Art. 34(4)(a)(i) PCT).

Re item V.

1. *Novelty (Art. 33(2) PCT):*

As the prior art does not teach the prevention of testicular BVDV infection, the subject-matter of claims 1-18 is novel.

2. *Inventive step (Art. 33(3) PCT):*

The invention solves the problem of preventing the spread of BVDV infection through semen. This is achieved by preventing testicular BVDV infection by vaccination against BVDV. Although testicular BVDV infection and vaccination against BVDV are known in the art, there appears to be a prejudice against the prevention of testicular BVDV infection by vaccination against BVDV as testes, being an immunoprivileged site, are considered to be excluded from immunoprotection resulting from vaccination. Hence, the subject-matter of claims 1-18 is considered to involve an inventive step.

3. *Industrial applicability (Art. 33(4) PCT):*

3.1 For the assessment of the present claims 1-9 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

3.2 The subject-matter of claims 10-18 is considered industrial applicable.

CLAIMS

9. The method of claim 8 wherein said additional antigens comprise Bovine Herpes Virus (BHV-1), Parainfluenza Virus Type 3 (PIV3), and Bovine Respiratory Syncytial Virus (BRSV).

10. The use of a vaccine selected from the group consisting of an inactivated type 1 BVDV vaccine, an inactivated type 2 BVDV vaccine, a modified live type 1 BVDV vaccine, and a modified live type 2 BVDV vaccine for manufacture of a medicament for preventing testicular BVDV infection in a susceptible male animal at increased risk of BVDV testicular infection

11. The use of claim 10 wherein the animal is selected from the group consisting of bulls, rams and boars.

12. The use of claim 11 wherein the animal is a bull.

13. The use of claim 10 wherein the vaccine comprises both a modified live type 1 BVDV vaccine and a modified live type 2 BVDV vaccine.

14. The use of claim 13 wherein at least one modified live BVDV vaccine is derived from a cytopathogenic virus.

15. The use of claim 13 wherein at least one modified live BVDV vaccine is derived from a non-cytopathogenic virus.

16. The use of claim 13 wherein both modified live BVDV vaccines are derived from a cytopathogenic virus.

17. The use of claim 10-16 wherein the vaccine comprises at least one additional antigen selected from the group consisting of Bovine Herpes Virus (BHV-1); Parainfluenza Virus Type 3 (PIV3); . Bovine Respiratory Syncytial Virus (BRSV); *Leptospira canicola,*

Leptospira grippotyphosa, Leptospira borgpetersenii hardio-prajitno, Leptospira icterohaemmorrhagia, Leptospira interrogans pomona, Leptospira borgpetersenii hardjo-bovis, Leptospira Bratislava, Campylobacter fetus, Mannheimia (Pasteurella) haemolytica, Pasteurella multocida, Mycobacterium bovis, and *Mycobacterium dispar.*

18. The use of claim 17 wherein said additional antigens comprise Bovine Herpes Virus (BHV-1), Parainfluenza Virus Type 3 (PIV3), and Bovine Respiratory Syncytial Virus (BRSV).